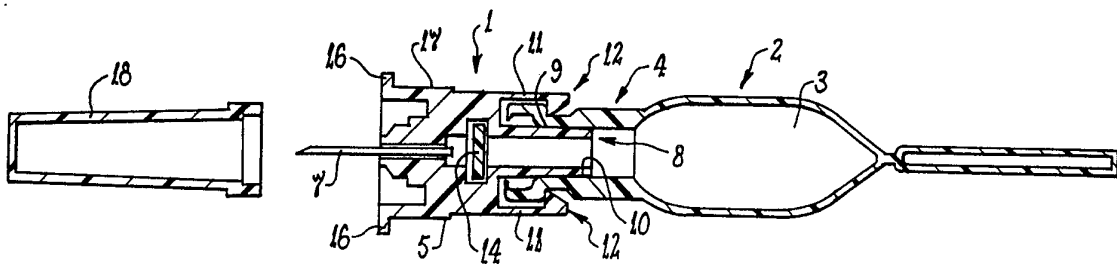




INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<p>(51) International Patent Classification ⁵ : A61M 5/28, 5/34</p>	<p>A1</p>	<p>(11) International Publication Number: WO 93/09826 (43) International Publication Date: 27 May 1993 (27.05.93)</p>
<p>(21) International Application Number: PCT/US92/09260 (22) International Filing Date: 4 November 1992 (04.11.92) (30) Priority data: PK 9506 15 November 1991 (15.11.91) AU (71) Applicant (for BF BJ CF CG CI CM GA GN LK MG ML MN MR MW SD SN TD TG only): THE UPJOHN COMPANY [US/US]; 301 Henrietta Street, Kalamazoo, MI 49001 (US). (71) Applicant (for all designated States except BF BJ CF CG CI CM GA GN LK MG ML MN MR MW SD SN TD TG): DELTA WEST PTY. LIMITED [AU/AU]; 15 Brodie Hall Drive, Technology Park, Bentley, W.A. 6102 (AU).</p>		<p>(72) Inventors; and (75) Inventors/Applicants (for US only): UNSWORTH, Rodney, William [AU/AU]; 7 Vix Street, Dalkeith, W.A. 6009 (AU). CARTER, Stephen, John [GB/AU]; 47 Foresthill Drive, Kingsley, W.A. 6026 (AU). (74) Agents: WILLIAM, Sidney, B., Jr., et al.; 301 Henrietta Street, Kalamazoo, MI 49001 (US). (81) Designated States: AT, BB, BG, BR, CA, CS, FI, HU, JP, KP, KR, LK, MG, MN, MW, NO, PL, RO, RU, SD, US, European patent (AT, BE, CH, DE, DK, ES, FR, GB, GR, IE, IT, LU, MC, NL, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, SN, TD, TG). Published <i>With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.</i></p>

(54) Title: AN INJECTION DEVICE



(57) Abstract

The present invention provides an injection device (1) adapted to engage a deformable plastic ampoule (2) having a reservoir (3) and a neck portion (4), said device comprising: a body (5) having a continuous fluid conduit (6) therethrough, the fluid conduit comprising at one end a male frusto-conical extending member (8) forming a sealing surface with a corresponding parallel-walled or frusto-conical female recess (10) on the neck portion (4) of said ampoule (2) when the ampoule and the device are cooperatively engaged. This device is simple to use and is suitable for self-injection by patients.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AT	Austria	FR	France	MR	Mauritania
AU	Australia	GA	Gabon	MW	Malawi
BB	Barbados	GB	United Kingdom	NL	Netherlands
BE	Belgium	GN	Guinea	NO	Norway
BF	Burkina Faso	GR	Greece	NZ	New Zealand
BG	Bulgaria	HU	Hungary	PL	Poland
BJ	Benin	IE	Ireland	PT	Portugal
BR	Brazil	IT	Italy	RO	Romania
CA	Canada	JP	Japan	RU	Russian Federation
CF	Central African Republic	KP	Democratic People's Republic of Korea	SD	Sudan
CG	Congo	KR	Republic of Korea	SE	Sweden
CH	Switzerland	KZ	Kazakhstan	SK	Slovak Republic
CI	Côte d'Ivoire	LI	Liechtenstein	SN	Senegal
CM	Cameroon	LK	Sri Lanka	SU	Soviet Union
CS	Czechoslovakia	LU	Luxembourg	TD	Chad
CZ	Czech Republic	MC	Monaco	TG	Togo
DE	Germany	MG	Madagascar	UA	Ukraine
DK	Denmark	ML	Mali	US	United States of America
ES	Spain	MN	Mongolia	VN	Viet Nam
FI	Finland				

- 1 -

AN INJECTION DEVICE

The present invention relates to an injection device for medical or veterinary injection. It will be convenient to describe the invention in relation to injection devices for self injection by relatively unskilled operators to treat medical conditions although it will be appreciated that the invention has much wider application.

Numerous medical conditions require treatment of a patient by self injection of drug, for example insulin-dependant diabetes is generally treated by self injection of insulin; male erectile impotence is often treated by way of intracavernosal injection of erectile impotence treating drugs. In both the above medical conditions self injection is generally by way of insulin syringes. These syringes are long and thin and usually have a fine gauge needle already attached to the syringe during manufacture. While such needles may be adequate for young dextrous hands which can manipulate this type of syringe, they can be cumbersome and very difficult to handle by older or infirm persons with limited coordination and who may also be afflicted with complaints such as arthritis which may further effect dexterity. Moreover, with the insulin type syringe, it is necessary for the user to have a relatively wide extension between the thumb and index finger to manipulate and actuate the syringe properly. This may cause a problem with older users who cannot easily extend their thumb or index finger across a broad extension to manipulate an insulin type syringe.

Other risks are associated with injection of substances. First, particularly in cases of intravenous injection there exists the danger of injecting air and causing embolism. Secondly, there is a danger of drawing up physiological fluids or the drug just injected upon completion of injection or if the injecting pressure is released during injection.

Furthermore there is nearly always a risk of

- 2 -

contamination of the injection apparatus by handling or exposure to the environment.

This risk is not only present where an unskilled operator is involved, but also where a skilled practitioner is acting in adverse conditions such as accident or emergency scenes or war zones.

Accordingly, there is a need to provide an injection device suitable for use in self injection by inexperienced patients or by patients with limited flexibility and coordination. Further, there is a need to provide an injection device which reduces the possibility of contamination during handling, which reduces or eliminates the risk of injecting air and causing an embolism in the patient, and which reduces the risk of drawing up physiological fluids during or upon completion of injection. Such a device should be simple to use and inexpensive to produce.

It is an object of the present invention to provide a solution to one or more of the above needs.

According to the present invention there is provided an injection device adapted to engage a deformable plastic ampoule having a reservoir and a neck portion, said device comprising;

a body having a continuous fluid conduit therethrough, the fluid conduit comprising at one end of said body an injection needle, and at the other end a male frusto-conical extending member tapering away from said body, the outer surface of said member forming a sealing surface with a corresponding parallel walled or frusto-conical female recess on the neck portion of said ampoule when the ampoule and device are cooperatively engaged.

The injection device is adapted to engage with and form a fluid-tight seal with a deformable plastic ampoule so that after the injection device and ampoule are cooperatively engaged the needle is inserted into the patient and the ampoule is squeezed to express its contents through the needle into the patient.

The body of the injection device may be any suitable

- 3 -

size or shape but is preferably of a suitable size to allow easy manipulation, especially by an inexperienced or elderly patient. At one end of the body there is located an injection needle having a fluid conduit passing therethrough, the needle of the kind well known in the art. Different devices made in accordance with the present invention may utilize different types of needles, depending upon the intended use of the device. For example if the device is for intercavernosal injection, a very fine grade needle is utilized, whereas if the device is for deep intramuscular injection, a thick, longer needle will be utilized. Preferably the needle is permanently connected to the body when the body is manufactured. A removable protective cap is preferably provided to cover the needle until the device is required for use. The protective cap may be a screw-on cap which engages with threads adjacent the needle, or the cap may engage an area adjacent the needle by friction fit or the like.

The male frusto-conical extending member at the other end of the body is adapted to engage a corresponding parallel walled or frusto-conical female recess on an ampoule. Preferably the fitting between the male member and female recess is a luer, which comprises a male cone with a conicity of 6:100 cooperating with a corresponding female cone on the ampoule. However, other conicities may be suitable provided that a fluid-tight seal is formed when the ampoule is engaged with the injection device.

When the injection device and deformable ampoule are connected, importantly the male member is inserted into the neck of the ampoule which has either a parallel walled or frusto-conical shaped recess in the neck. The ampoule is generally of the kind being blow-moulded from a thermoplastics material such as polypropylene, polyethylene or a blend thereof as is commonly used in the art, and having a cap portion joined to the neck of the ampoule by a frangible web or the like. An advantage of the present invention is that once the ampoule is opened by snapping off the cap, the surface of the ampoule which

- 4 -

mates with the injection device is on the inside of the ampoule, rather than on the outside of the ampoule which is the case with known injection devices. The engagement with the inside of the ampoule significantly reduces the risk of contamination as a result of handling of the ampoule, as the surfaces of the ampoule exposed to the fingers of the user do not come into contact with the fluid conduit through the injection device, and do not form part of the sealing surfaces with the injection device.

The injection device may be provided with an annular collar radially spaced from and at least partially surrounding the male extending member. The annular collar may operate as a shield to protect the male member from contact with the user's fingers and hence protects from the risk of contamination. The annular collar must be suitably spaced from the male member to allow sufficient clearance for the neck portion of the ampoule when positioned over the male member. Preferably the annular collar does not totally surround the male member such that a part of the male member protrudes from the collar to facilitate location of the ampoule about the male member.

In a preferred embodiment the annular collar includes one or more barbs which project inwardly towards the male member. Upon engagement of the ampoule with the male member the barb or barbs engage the outside of the neck portion of the ampoule to prevent removal of the ampoule. In one embodiment, when the male member is of the luer lock type and it is necessary to twist the ampoule onto the injection device, the barb(s) are configured to prevent unscrewing of the ampoule from the device. The barbs will preferably deform the neck of the ampoule by cutting or biting into the neck or otherwise scoring the neck when the ampoule is twisted onto the injection device. Similarly, if a luer slip type connection is present between the ampoule and injection device, such deformation of the ampoule neck may occur when the ampoule is simply pushed onto the male member. The advantage of such non-removable engagement between the

- 5 -

injection device and ampoule is that the device is capable of being used only once, and therefore the risk of cross-infection from multiple uses is eliminated.

The barb(s) preferably have a surface distal the
5 body of the injection device which slope inward toward the body. These sloping surfaces assist in locating the neck of the ampoule about the device and act as guides to centre the ampoule neck about the male member. The sloping surfaces also assist in enabling the ampoule to be
10 pushed onto the injection device.

Preferably two barbs are provided on the collar the barbs being positioned opposite each other on the collar. Cut-out portions may be provided in the collar, preferably adjacent each barb.

15 The configuration of the present invention further improves over the converse arrangement known in the prior art i.e. where an ampoule has a male neck insertable into a female recess in the injection device. In the present invention where the ampoule is made from a relatively
20 pliable thermoplastic material and the majority of the injection device is made from a rigid thermoplastic material the locking mechanism between the injection device and ampoule is considerably more effective as the locking barbs are formed on the injection device from the
25 relatively rigid material, rather than on the ampoule from a softer material; the latter arrangement not being as secure as the former.

In another embodiment of the present invention there may be provided a valve means in the fluid conduit between
30 the male member and needle. The valve may be any suitable valve means known in the art and may be positioned to permit flow of fluid along the fluid conduit from the male member to the needle, but to prevent flow from the needle back to the male member. Particularly in relation to
35 intracavernosal self-injection it is undesirable for physiological fluids to be drawn back into the injection device and the valve means is adapted to prevent such back flow. In some applications however, such as dental injection, it is desirable to withdraw physiological

- 6 -

fluids into the injection device to ascertain whether or not a blood vessel has been struck. In such applications the valve means will not be present, and preferably the injection device will be made from a transparent material so that the colour of any physiological fluid withdrawn
5 can be noted.

In another aspect of the present invention there is provided stop means to limit penetration of the needle into the patient. Particularly in cases of self injection
10 it is desirable that the needle penetrate the patient only to a limited extent. Preferably the stop means comprises a flange which extends from the body to allow a predetermined length of the needle to protrude from the body beyond the flange. During injection the needle is
15 inserted into a patient, to a point where the flange abuts the skin of the patient, preventing further insertion.

The injection device of the present invention is suitable for but not limited to intramuscular, intravenous, subcutaneous and intracavernosal injection
20 although it may also be suitable for blood-taking if the ampoule is suitably configured to allow a vacuum to be applied to the needle. The ampoule adapted for use with the present invention may contain any suitable substance for injection, including drug solutions such as narcotics,
25 anaesthetics and hormones etc., sodium chloride solutions, potassium chloride solutions, water or the like.

DESCRIPTION OF THE DRAWINGS

It is to be
30 understood that the drawings and following description relate to a preferred embodiment only, and are not intended to limit the scope of the invention.

Figure 1 is an axial cross-section of an injection device made in accordance with the present invention.

35 Figure 2 is an axial cross-section of the ampoule engaging end of an injection device of Figure 1.

Figure 3 is an end elevation of an injection device of Figure 1 showing the ampoule engaging end.

Figure 4 is an axial cross-section of an injection

- 7 -

device of Figure 1 with an ampoule attached.

Injection device 1 is adapted to engage a deformable plastic ampoule 2 having a reservoir 3 and a neck portion 4. The injection device 1 has a body 5 having a continuous fluid conduit 6 therethrough. The continuous fluid conduit comprises at one end an injection needle 7 and at the other end a male frusto-conical extending member 8 which tapers away from body 5. The outer surface of member 8 forms a sealing surface with a corresponding frusto-conical female recess 10 on the neck portion 4 of ampoule 2.

Male member 8 and conical female recess 10 are preferably cooperating male and female luer cones.

An annular collar 11 spaced from member 8 is provided which at least partially surrounds member 8 and reduces the risk of member 8 from being touched by the fingers of the user. Collar 11 includes a plurality of barbs 12 which project inwardly towards member 8 and which engage the outside of the neck portion 4 of the ampoule 2. The surface 13 of each barb 12 which is distal the body 5 slopes inwardly towards the body to facilitate easy coupling of the ampoule 2 and injection device 1.

The portions of collar adjacent each barb 8 may be cut-out (not shown).

Valve member 14 may be provided in fluid conduit 6 in a valve chamber 15. Valve member 14 may be a resilient slideable plug or the like.

Stop means 16 comprises an annular flange extending from body 5 on an annular collar 17. Stop means 16 allows a predetermined length of needle 7 to extend beyond the flange.

A protective cap 18 may be provided to protect needle 7. Cap 18 may engage members 19 by friction fit and can be removed and replaced easily by the user.

In use ampoule 2 is opened by removing the frangible cap covering neck 4, thus exposing female recess 10. Neck portion 4 is brought into contact with and centered about male member 8 and fitted between male member 8 and annular collar 11. The end of neck 4 is guided into a central

- 8 -

position by the sloping surfaces 13 of each barb 12.

The ampoule 2 and injection device 1 are then pushed together such that surfaces 9 and 10 engage and seal against one another. If the injection device 1 comprises a luer slip fitting, ampoule 2 is simply pushed onto the male member 1, but if the injection device has a luer lock fitting, ampoule 2 is pushed and twisted onto male member 1.

In the process of connecting the ampoule 2 and injection device 1 barbs 12 grip and deform neck 4 so that the ampoule cannot readily be removed once attached. Any resilience in neck 4 will allow a tight seal between female recess 10 and male member 8.

Cap 18 is then removed and needle 7 is inserted into the patient until the skin of the patient comes into contact with stop means 16 such that further penetration of the needle is prevented. The user then squeezes the side walls of ampoule 2 to eject fluid from the reservoir 3 through fluid conduit 6, past valve 14 (where present) and out of needle 7.

Where valve 14 is present, backflow of physiological fluid towards ampoule 2 is prevented when valve 14 seals the fluid conduit 6.

Upon complete discharge of the ampoule's contents, the needle 7 is withdrawn and cap 18 is replaced. The spent injection device and ampoule is then disposed of in an appropriate manner.

The injection device may be made from any suitable material, preferably a sterilizable thermoformable plastic material such as polycarbonate. The invention is particularly suitable when the ampoule is made from a pliable polypropylene, polyethylene or a blend thereof as is commonly used in the art. The injection device may be manufactured by any suitable means known to those skilled in the art such as injection moulding or the like.

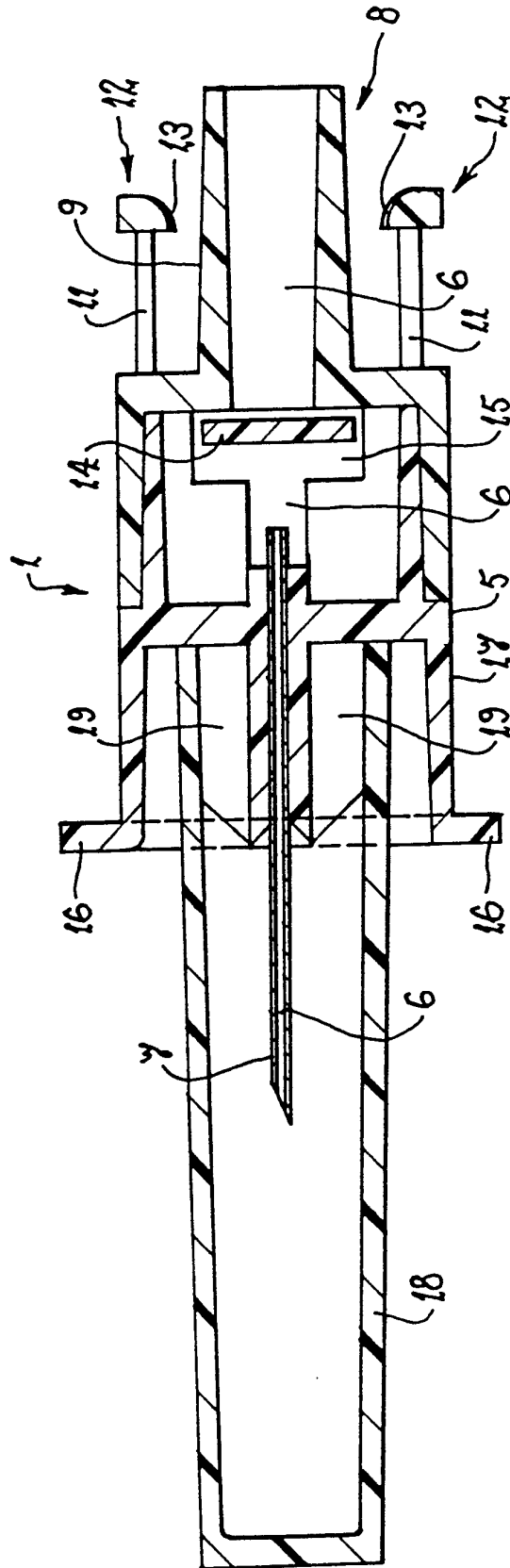
It is to be understood that various modifications, additions and/or alterations may be made to the parts previously described without departing from the ambit of the present invention.

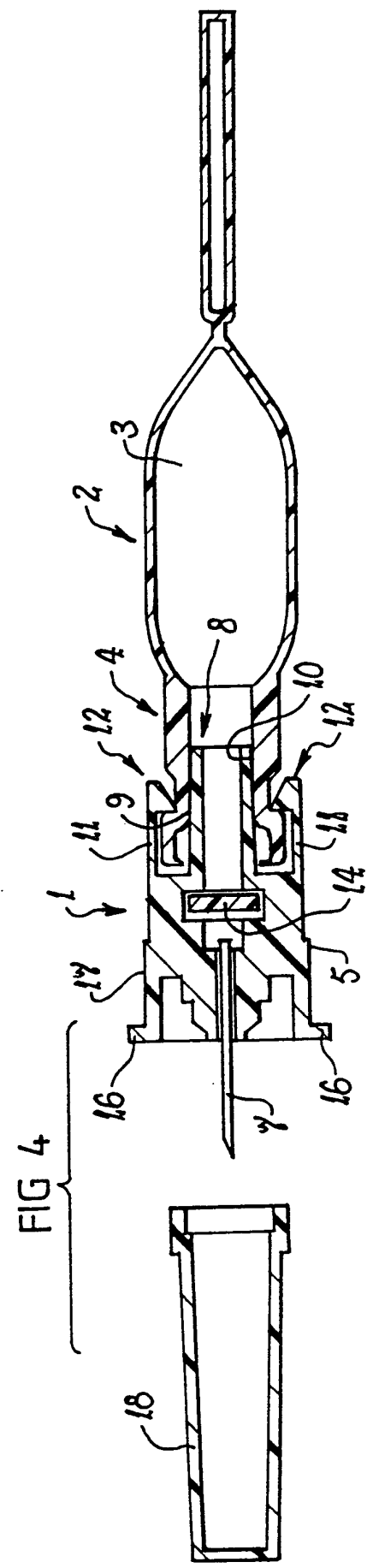
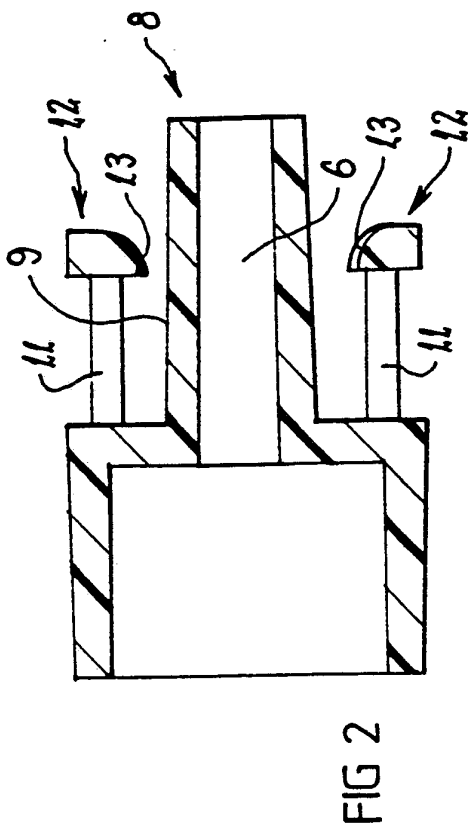
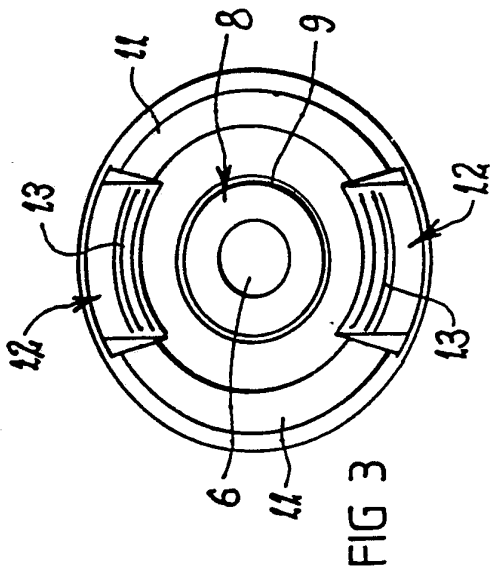
CLAIMS

1. An injection device comprising an integral injection needle and needle connecting assembly, said needle connecting assembly being of unitary construction and comprising a body portion having a continuous fluid conduit extending
5 therethrough, said fluid conduit comprising said injection needle at a distal end of said body portion and an outwardly extending male frusto-conical member at a proximal end of said body portion, said injection needle comprising means for subcutaneously delivering a medicament and said male frusto-conical member having an annular collar provided therearound comprising means for engaging with
10 an outer surface of a neck portion of a flexibly deformable ampoule containing said medicament and an outer surface comprising means for sealingly engaging with an inner surface of said ampoule neck portion.
2. The injection device of Claim 1, wherein said means for engaging with an
15 outer surface of a neck portion of the flexibly deformable ampoule comprises one of more barbed members.
3. The injection device of Claim 2, wherein said barbed members have an inner surface which slopes radially inward towards said body portion and are
20 provided distal to said injection needle.
4. The injection device of Claim 2, wherein said annular collar includes one or more cut-out portions provided adjacent to each barbed member.
- 25 5. The injection device of Claim 2, wherein two barbed members are mounted opposite to each other on said annular collar.
6. The injection device of Claim 2, wherein the barbed members prevent the removal of said ampoule once said ampoule and said injection device are
30 cooperatively engaged.
7. The injection device of Claim 1, additionally comprising means for limiting the depth of insertion of the injection needle.

-10-

8. The injection device of Claim 7, wherein said means for limiting the depth of insertion of the injection needle comprises a flange member provided at a desired location along the length of said injection needle.
- 5 9. The injection device of Claim 1, wherein said outer surface of said ampoule neck portion and said means for engaging with said outer surface of said ampoule neck portion comprise cooperative luer fittings.
- 10 10. The injection device of Claim 1, wherein a one-way valve is provided in said fluid conduit.
- 15 11. An injection device comprising an integral injection needle and needle connecting assembly and ampoule combination, said needle connecting assembly being of unitary construction and comprising a body portion having a continuous fluid conduit extending therethrough, said fluid conduit comprising said injection
20 needle at a distal end of said body portion, an outwardly extending male frusto-conical member at a proximal end of said body portion and having a one-way valve provided therein, said injection needle comprising means for subcutaneously delivering a medicament and said male frusto-conical member having an annular collar provided therearound which is engaged with an outer surface of a neck portion of said ampoule and an outer surface sealingly engaged with an inner surface of said ampoule neck portion, said ampoule being flexibly deformable.





I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) ⁶												
According to International Patent Classification (IPC) or to both National Classification and IPC Int.Cl. 5 A61M5/28; A61M5/34												
II. FIELDS SEARCHED												
Minimum Documentation Searched ⁷												
Classification System	Classification Symbols											
Int.Cl. 5	A61M											
Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched ⁸												
III. DOCUMENTS CONSIDERED TO BE RELEVANT ⁹												
Category ¹⁰	Citation of Document, ¹¹ with indication, where appropriate, of the relevant passages ¹²	Relevant to Claim No. ¹³										
Y	US,A,2 828 743 (ASHKENAZ ET AL.) 1 April 1958 see column 2, line 37 - line 46 see column 3, line 31 - line 33; figures 1,2,5	1,2,4,6, 9-11										
A	---	11										
Y	EP,A,0 356 679 (ING. ERICH PFEIFFER GMBH & CO. KG) 7 March 1990 see column 7, line 52 - line 58; figures 1,3	1,2,4,6, 9-11										
A	---	2,3,5										
	US,A,4 568 336 (COOPER) 4 February 1986 see column 3, line 52 - line 53; figures 2,4											

		-/--										
¹⁰ Special categories of cited documents : <table border="0"> <tr> <td>"A" document defining the general state of the art which is not considered to be of particular relevance</td> <td>"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention</td> </tr> <tr> <td>"E" earlier document but published on or after the international filing date</td> <td>"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step</td> </tr> <tr> <td>"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)</td> <td>"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.</td> </tr> <tr> <td>"O" document referring to an oral disclosure, use, exhibition or other means</td> <td>"&" document member of the same patent family</td> </tr> <tr> <td>"P" document published prior to the international filing date but later than the priority date claimed</td> <td></td> </tr> </table>			"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention	"E" earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step	"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.	"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family	"P" document published prior to the international filing date but later than the priority date claimed	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention											
"E" earlier document but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step											
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.											
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family											
"P" document published prior to the international filing date but later than the priority date claimed												
IV. CERTIFICATION												
Date of the Actual Completion of the International Search	Date of Mailing of this International Search Report											
16 MARCH 1993	02.04.93											
International Searching Authority	Signature of Authorized Officer											
EUROPEAN PATENT OFFICE	SEDY R.											

III. DOCUMENTS CONSIDERED TO BE RELEVANT (CONTINUED FROM THE SECOND SHEET)		Relevant to Claim No.
Category °	Citation of Document, with indication, where appropriate, of the relevant passages	
A	FR,A,2 089 176 (BECTON DICKINSON AND COMPANY) 7 January 1972 see page 7, line 21; figures 1,2 -----	7,8

**ANNEX TO THE INTERNATIONAL SEARCH REPORT
ON INTERNATIONAL PATENT APPLICATION NO.**

US 9209260
SA 66908

This annex lists the patent family members relating to the patent documents cited in the above-mentioned international search report. The members are as contained in the European Patent Office EDP file on The European Patent Office is in no way liable for these particulars which are merely given for the purpose of information. 16/03/93

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US-A-2828743		None	
EP-A-0356679	07-03-90	DE-A- 3827335	15-02-90
US-A-4568336	04-02-86	None	
FR-A-2089176	07-01-72	DE-A, B 2115090	21-10-71
		GB-A- 1297750	29-11-72
		SE-B- 384629	17-05-76
		US-A- 3677245	18-07-72